

PATENT
Attorney Docket No. **DHI-08810**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: David R. Scholl *et al.*

Serial No.: 10/813,852

Filed: 03/30/04

Entitled: **MIXED CELL DIAGNOSTIC SYSTEMS**

Group No.:

Examiner:

TRANSMITTAL LETTER

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

CERTIFICATE OF MAILING UNDER 37 CFR § 1.8(a)

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By: 

Chit Cannon-Clin

Sir or Madam:

Enclosed please find an Information Disclosure Statement, Form PTO-1449 and copy of 28 references for filing in the U.S. Patent and Trademark Office.

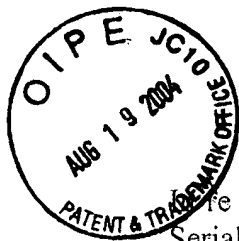
The Commissioner is hereby authorized to charge any fee or credit overpayment related to this filing to our Deposit Account No. 08-1290. An originally executed duplicate of this transmittal is enclosed for this purpose.

Dated: August 17, 2004

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Cliff Cannon-Cin

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The citations listed below may be material to the examination of the above-identified application, and are therefore submitted in compliance with the duty of disclosure defined in 37 C.F.R. §§ 1.56 and 1.97. The Examiner is requested to make these citations of official record in this application.

In accordance with 37 CFR § 1.98(d), a copy of the references numbered as 10-24 in the attached PTO-1449 is **not** provided since it was previously submitted to the Office in prior application serial number 10/407,789 (our file DHI-07937), which is relied upon for an earlier filing date under USC §120.

The following citations are referred to in the body of the specification:

- Boshart *et al.*, "A Very Strong Enhancer Is Located Upstream of an Immediate Early Gene of Human Cytomegalovirus," *Cell* 41:521-530 (1985);
- Dijkema *et al.*, "Cloning and Expression of the Chromosomal Immune Interferon Gene of the Rat," *EMBO J.* 4:761-767 (1985);

- Gorman *et al.*, "The Rous Sarcoma Virus Long Terminal Repeat is a Strong Promoter When Introduced into a Variety of Eukaryotic Cells by DNA-mediated Transfection," *Proc. Natl. Acad. Sci. USA* 79:6777-6781 (1982);
- Kim *et al.*, "Use of the human elongation factor 1 α promoter as a versatile and efficient expression system," *Gene* 91:217-223 (1990);
- Leland, *Clinical Virology*, W.B. Saunders Company, Philadelphia, PA at pp. 60-65, and 85-86 (1996);
- Maniatis *et al.*, "Regulation of Inducible and Tissue-Specific Gene Expression," *Science* 236:1237 (1987);
- Mizushima and Nagata, "pEF-BOS, a powerful mammalian expression vector," *Nuc. Acids. Res.* 18:5322 (1990);
- Olsen *et al.*, "Isolation of Seven Respiratory Viruses in Shell Vials: a Practical and Highly Sensitive Method," *J. Clin. Microbiol.* 31:422-425 (1993);
- Rabalais *et al.*, "Rapid Diagnosis of Respiratory Viral Infections by Using a Shell Vial Assay and Monoclonal Antibody Pool," *J. Clin. Microbiol.*, 30:1505-1508 (1992);
- Sambrook *et al.*, *Molecular Cloning: A Laboratory Manual*, 2nd ed., Cold Spring Harbor Laboratory Press, New York, pp. 16.6-16.15 (1989);
- Schmidt and Emmons, "General Principles of Laboratory Diagnostic Methods for Viral, Rickettsial, and Chlamydial Infections," in Schmidt and Emmons (eds.), *Diagnostic Procedures for Viral, Rickettsial and Chlamydial Infections*, American Public Health Association, Washington, D.C., page 4 (1989);
- Smith *et al.*, "Detection of Respiratory Syncytial virus in Nasopharyngeal Secretions by Shell Vial Technique," *J. Clin. Microbiol.* 29:463-465 (1991);
- Uetsuki *et al.*, "Isolation and Characterization of the Human Chromosomal Gene for Polypeptide Chain Elongation Factor-1 α ," *J. Biol. Chem.* 264:5791-5798 (1989);
- Voss *et al.*, "The role of enhancers in the regulation of cell-type-specific transcriptional control," *Trends Biochem. Sci.* 11:287-289 (1986); and
- Wiedbrauk and Johnston, *Manual of Clinical Virology*, Raven Press, Inc., New York, NY, pp. 1-17, and 64-76 (1993).

A copy of the following citations, numbered as 1 and 25-39 in the PTO-1449, copies **not** attached, were submitted in Information Disclosure Statements which were mailed to the Office on 8/30/99 and 4/19/2000 in the prior application Serial No. 09/066,072 (our file DHI-03315):

- Dagan and Menegus, "A combination of four cell types for rapid detection of enteroviruses in clinical specimens," *J. Med. Virol.* 19: 219-228 (1986);
- Chonmaitree *et al.*, "Comparison of Cell Cultures for Rapid Isolation of Enteroviruses," *J. Clin. Microbiol.* 26:2576-2580 (1988);
- Castells *et al.*, "NCI-H292 as an Alternative Cell Line for the Isolation and Propagation of the Human Paramyxoviruses," *Arch. Virol.* 115:277-288 (1990);
- Brumback and Wade, "Simultaneous Rapid Culture for Four Respiratory Viruses in the Same Cell Monolayer Using a Differential Multicolored Fluorescent Confirmatory Stain," *J. Clin. Microbiol.* 34:798-801 (1996);
- Gleaves *et al.*, "Detection of Human Cytomegalovirus in Clinical Specimens by Centrifugation Culture with a Nonhuman Cell Line," *J. Clin. Microbiol.* 30:1045-1048 (1992);
- Hierholzer *et al.*, "Sensitivity of NCI-H292 Human Lung Mucoepidermoid Cells for Respiratory and Other Human Viruses," *J. Clin. Microbiol.* 31:1504-1510 (1993);
- Klespies *et al.*, "Detection of enteroviruses from clinical specimens by spin amplification shell vial culture and monoclonal antibody assay," *J. Clin. Microbiol.* 34:1465-1467 (1996);
- Leonardi *et al.*, "Use of Continuous Human Lung Cell Culture for Adenovirus Isolation," *Intervirology* 38:352-355 (1995);
- ViroMED Laboratories, Inc. Pamphlet entitled, "ViroMed Cell Culture Products (1996);
- Navarro-Mari *et al.*, "Rapid Detection of Respiratory Viruses by Shell Vial Assay Using Simultaneous Culture of HEp-2, LLC-MK2, and MDCK Cells in a Single Vial," *J. Clin. Microbiol.* 37: 2346-2347 (1999);
- U.S. Patent No. 5,939,253, issued 08/17/99 to Scholl *et al.*;

- Benton & Hurst (1986) "Evaluation of mixed cell types and 5-iodo-2'-deoxyuridine treatment upon plaque assay titers of human enteric viruses," *Applied and Environmental Microbiology* 51:1036-1040;
- Miller *et al.* (1969) "Clinical virology and viral surveillance in a pediatric group practice: The use of double-seeded tissue culture tubes for primary virus isolation," *Am. J. Epidemiol.* 88:245-256;
- Schindler *et al.*, "Investigation of ELVIS Technology for use in HSV Typing of Clinical Specimens," Abstract, 11th Annual Clinical Virology Symposium, May 1, 1995, Clearwater Beach, FL.;
- Jollick *et al.*, "Typing of HSV with the ELVIS HSV typing system: differential staining characteristics do not result from promoter-transactivator specificity," Abstract, 12th Annual Clinical Virology Symposium, Clearwater FL (1996); and
- Astier-Gin *et al.* (1995) "Identification of HTLV-I- or HTLV-II-producing cells by cocultivation with BHK-21 cells stably transfected with a LTR-lacZ gene construct," *J. Virological Methods* 51:19-30.

The citations listed in the accompanying form PTO-1449 as numbers 2-3 and 40-42, copies attached, were cited in the International Search Report in parent application PCT/US99/09015 filed 4/26/99 (our file DHI-03729).

- U.S. Patent No. 4,224,412 issued 9/23/80 to Dorofeev *et al.*;
- U.S. Patent No. 5,418,132 issued 5/23/95 to Olivo;
- Rabalais *et al.* (1992) "Rapid Diagnosis of Respiratory Viral Infections by Using a Shell Vial Assay and Monoclonal Antibody Pool," *J. Clin. Microbiol.* 30:1505-1508;
- Smith *et al.* (1991) "Detection of Respiratory Syncytial virus in Nasopharyngeal Secretions by Shell Vial Technique," *J. Clin. Microbiol.* 29:463-465; and
- Heggie *et al.* (1993) "Rapid detection of herpes simplex virus in culture by in situ hybridization, *J. Virol. Meth.* 41:1-7.

The citations listed in the accompanying form PTO-1449 as numbers 4-5 and 43, copies attached, were cited in the International Preliminary Examination Report in parent application PCT/US99/09015 filed 4/26/99 (our file DHI-03729).

- U.S. Patent No. 5,262,359 issued 11/16/93 to Hierholzer;
- U.S. Patent No. 4,193,991 issued 3/18/80 to Appel *et al.*; and
- Lennette *et al.* "Diagnostic Procedures for Viral and Rickettsia Infections," Amer. Publ. Health Assoc, Inc., 1969, Fourth Edition, pp 653-655, 659-660, and 570-572.

The citations listed in the accompanying form PTO-1449 as numbers 39 (copy **not** attached as it was submitted in Information Disclosure Statements which was mailed to the Office on 8/30/99 and 4/19/2000 in the prior application Serial No. 09/066,072 (our file DHI-03315)) and 44, (copy attached), were cited by OPIC in Canadian parent application no. 2,326,724 (our file DHI-04803):

- Astier-Gin *et al.* (1995) "Identification of HTLV-I- or HTLV-II-producing cells by cocultivation with BHK-21 cells stably transfected with a LTR-lacZ gene construct," J. Virol. Methods 51:19-30; and
- Fong *et al.* (1991) "Advantages of multiple cell culture systems for detection of mixed-virus infections," J. Virol. Methods 33:283-289.

The citations listed in the accompanying form PTO-1449 as numbers 9 (copy attached), 35 (copy **not** attached as it was submitted in Information Disclosure Statements which was mailed to the Office on 8/30/99 and 4/19/2000 in the prior application Serial No. 09/066,072 (our file DHI-03315)), and 45-50, copies attached, were cited by the European Patent Office in European parent application no. 99 920 029.8 (our file DHI-04848):

- Benton & Hurst (1986) "Evaluation of mixed cell types and 5-iodo-2'-deoxyuridine treatment upon plaque assay titers of human enteric viruses," Applied and Environmental Microbiology 51:1036-1040;
- Tougianidou *et al.* (1989) "Assessment of Various Cell Lines (including Mixed Cell Cultures) for the Detection of Enteric Viruses in Different Water Sources," Water Science and Tech. 21:311-314;

- Subrahmanyam *et al.* (1974) "The Development of Double Seeded and Mixed Cell Culture Systems for Use in Diagnostic Virology," Archiv Fuer Die Gesamte Virusforschung 44:291-297;
- Huang *et al.* (2000) "Application of mixed cell lines for the detection of viruses from clinical specimens," Clin. Microbiol. Newsletter 22:89-92;
- WO 97 24461 issued 7/10/97 to Huang;
- Reina *et al.* (1997) "Comparison of Madin-Darby canine kidney cells (MDCK) with a green monkey continuous cell line (Vero) and human lung embryonated cells (MRC-5) in the isolation of influenza A virus from nasopharyngeal aspirates by shell vial culture," J. Clin. Microbiol. 35:1900-1901;
- Schultz-Cherry *et al.* (1998) "Mink lung epithelial cells: Unique cell line that supports influenza A and B virus replication," J. Clin. Microbiol. 36:3718-3720; and
- Huang *et al.* (2000) "Mink lung cells and mixed mink lung and A549 cells for rapid detection of influenza virus and other respiratory viruses," J. Clin. Microbiol. 38:422-423.

The citations listed in the accompanying form PTO-1449 as numbers 51-52, copies attached, were cited by the Australian Patent Office in Australian parent application no. 37616/99 (our file DHI-04847):

- Rangan *et al.* (1972) "Detection and assay of feline leukemia virus (FeLV) by a mixed culture cytopathogenicity method," Virol. 47:247-250; and
- Karetnyi *et al.* (1982) "Use of a co-cultivation method for detecting cytomegalovirus contamination of cell cultures of simian origin," Voprosy Virusdogii 27(2), Abstract.

Applicant has become aware of the following printed publications, copies attached, which may be material to the examination of this application:

- U.S. Patent No. 6,168,915 issued 1/2/01 to Scholl *et al.*;
- U.S. Patent No. 6,376,172 issued 4/23/02 to Scholl *et al.*;
- U.S. Patent No. 6,573,080 issued 6/3/03 to Scholl *et al.*;

PATENTAttorney Docket No. **DHI-08810**

- Scholl *et al.*, U.S. Application No. 20030215796 published 11/20/03;
- Chan *et al.* (2003) "Human Metapneumovirus Detection in Patients with Severe Acute Respiratory Syndrome," *Emerging Infect. Dis.* 9:1058-1063;
- Frank *et al.* (1979) "Comparison of Different Tissue Cultures for Isolation and Quantitation of Influenza and Parainfluenza Viruses," *J. Clin. Microbiol.* 10:32-36;
- Setterquist *et al.* "A Comparison of LLC-MK2 and R-Mix™ (A549, MV1lu) Cells for the Detection of Human Metapneumovirus," 19th Annual Clinical Virology Symposium, Clearwater, FL, April 27-30, 2003;
- Genomes, T.A. Brown, Wiley-Liss, 1994, page 179;
- Biochemistry, Third Edition, W.H. Freeman and Company, NY, 1988, page 98; and
- The Encyclopedia of Molecular Biology, Blackwell Science, 1994, page 225.

This Information Disclosure Statement under 37 C.F.R. §§ 1.56 and 1.97 is not to be construed as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that any one or more of these citations constitutes prior art.

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(Modified)U.S. Department of Commerce
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use Several Sheets If Necessary)

(37 CFR § 1.98(b))

Applicant: David R. Scholl *et al.*

Filing Date: 03/30/04

Group Art Unit:

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.	Serial / Patent Number	Issue Date	Applicant / Patentee	Class	Subclass	Filing Date
	1	5,939,253	08/17/99	Scholl <i>et al.</i>			
	2	4,224,412	9/23/80	Dorofeev <i>et al.</i>			
	3	5,418,132	5/23/95	Olivo			
	4	5,262,359	11/16/93	Hierholzer			
	5	4,193,991	3/18/80	Appel <i>et al.</i>			
	6	6,168,915	1/2/01	Scholl <i>et al.</i>			
	7	6,376,172	4/23/02	Scholl <i>et al.</i>			
	8	6,573,080	6/3/03	Scholl <i>et al.</i>			

FOREIGN PATENTS OR PUBLISHED FOREIGN PATENT APPLICATIONS

		Document Number	Publication Date	Country / Patent Office	Class	Subclass	Translation	
							Yes	No
	9	WO 97 24461	7/10/97	PCT				

OTHER DOCUMENTS (Including Author, Title, Date, Relevant Pages, Place of Publication)

*	10	Boshart <i>et al.</i> , "A Very Strong Enhancer Is Located Upstream of an Immediate Early Gene of Human Cytomegalovirus," <i>Cell</i> 41:521-530 (1985)
*	11	Dijkema <i>et al.</i> , "Cloning and Expression of the Chromosomal Immune Interferon Gene of the Rat," <i>EMBO J.</i> 4:761-767 (1985)
*	12	Gorman <i>et al.</i> , "The Rous Sarcoma Virus Long Terminal Repeat is a Strong Promoter When Introduced into a Variety of Eukaryotic Cells by DNA-mediated Transfection," <i>Proc. Natl. Acad. Sci. USA</i> 79:6777-6781 (1982)
*	13	Kim <i>et al.</i> , "Use of the human elongation factor 1 α promoter as a versatile and efficient expression system," <i>Gene</i> 91:217-223 (1990)
*	14	Leland, <i>Clinical Virology</i> , W.B. Saunders Company, Philadelphia, PA at pp. 60-65, and 85-86 (1996)
*	15	Maniatis <i>et al.</i> , "Regulation of Inducible and Tissue-Specific Gene Expression," <i>Science</i> 236:1237 (1987)
*	16	Mizushima and Nagata, "pEF-BOS, a powerful mammalian expression vector," <i>Nuc. Acids. Res.</i> 18:5322 (1990)
*	17	Olsen <i>et al.</i> , "Isolation of Seven Respiratory Viruses in Shell Vials: a Practical and Highly Sensitive Method," <i>J. Clin. Microbiol.</i> 31:422-425 (1993)
*	18	Rabalais <i>et al.</i> , "Rapid Diagnosis of Respiratory Viral Infections by Using a Shell Vial Assay and Monoclonal Antibody Pool," <i>J. Clin. Microbiol.</i> , 30:1505-1508 (1992)
*	19	Sambrook <i>et al.</i> , <i>Molecular Cloning: A Laboratory Manual</i> , 2nd ed., Cold Spring Harbor Laboratory Press, New York, pp. 16.6-16.15 (1989)
*	20	Schmidt and Emmons, "General Principles of Laboratory Diagnostic Methods for Viral, Rickettsial, and Chlamydial Infections," in Schmidt and Emmons (eds.), <i>Diagnostic Procedures for Viral, Rickettsial and Chlamydial Infections</i> , American Public Health Association, Washington, D.C., page 4 (1989)
*	21	Smith <i>et al.</i> , "Detection of Respiratory Syncytial virus in Nasopharyngeal Secretions by Shell Vial Technique," <i>J. Clin. Microbiol.</i> 29:463-465 (1991)
*	22	Uetsuki <i>et al.</i> , "Isolation and Characterization of the Human Chromosomal Gene for Polypeptide Chain Elongation Factor-1 α ," <i>J. Biol. Chem.</i> 264:5791-5798 (1989)
*	23	Voss <i>et al.</i> , "The role of enhancers in the regulation of cell-type-specific transcriptional control," <i>Trends Biochem. Sci.</i> 11:287-289 (1986)
*	24	Wiedbrauk and Johnston, <i>Manual of Clinical Virology</i> , Raven Press, Inc., New York, NY, pp. 1-17, and 64-76 (1993)

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(Use Several Sheets If Necessary)Applicant: David R. Scholl *et al.*

(37 CFR § 1.98(b))

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OTHER DOCUMENTS (Including Author, Title, Date, Relevant Pages, Place of Publication)

* 25	Dagan and Menegus, "A combination of four cell types for rapid detection of enteroviruses in clinical specimens," <i>J. Med. Virol.</i> 19: 219-228 (1986)
* 26	Chonmaitree <i>et al.</i> , "Comparison of Cell Cultures for Rapid Isolation of Enteroviruses," <i>J. Clin. Microbiol.</i> 26:2576-2580 (1988)
* 27	Castells <i>et al.</i> , "NCI-H292 as an Alternative Cell Line for the Isolation and Propagation of the Human Paramyxoviruses," <i>Arch. Virol.</i> 115:277-288 (1990)
* 28	Brumback and Wade, "Simultaneous Rapid Culture for Four Respiratory Viruses in the Same Cell Monolayer Using a Differential Multicolored Fluorescent Confirmatory Stain," <i>J. Clin. Microbiol.</i> 34:798-801 (1996)
* 29	Gleaves <i>et al.</i> , "Detection of Human Cytomegalovirus in Clinical Specimens by Centrifugation Culture with a Nonhuman Cell Line," <i>J. Clin. Microbiol.</i> 30:1045-1048 (1992)
* 30	Hierholzer <i>et al.</i> , "Sensitivity of NCI-H292 Human Lung Mucoepidermoid Cells for Respiratory and Other Human Viruses," <i>J. Clin. Microbiol.</i> 31:1504-1510 (1993)
* 31	Klespies <i>et al.</i> , "Detection of enteroviruses from clinical specimens by spin amplification shell vial culture and monoclonal antibody assay," <i>J. Clin. Microbiol.</i> 34:1465-1467 (1996)
* 32	Leonardi <i>et al.</i> , "Use of Continuous Human Lung Cell Culture for Adenovirus Isolation," <i>Intervirology</i> 38:352-355 (1995)
* 33	ViroMED Laboratories, Inc. Pamphlet entitled, "ViroMed Cell Culture Products (1996)
* 34	Navarro-Mari <i>et al.</i> , "Rapid Detection of Respiratory Viruses by Shell Vial Assay Using Simultaneous Culture of HEp-2, LLC-MK2, and MDCK Cells in a Single Vial," <i>J. Clin. Microbiol.</i> 37: 2346-2347 (1999)
* 35	Benton & Hurst (1986) "Evaluation of mixed cell types and 5-iodo-2'-deoxyuridine treatment upon plaque assay titers of human enteric viruses," <i>Applied and Environmental Microbiology</i> 51:1036-1040
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42 ✓	Heggie <i>et al.</i> (1993) "Rapid detection of herpes simplex virus in culture by in situ hybridization," <i>J. Virol. Meth.</i> 41:1-7
43 ✓	Lennette <i>et al.</i> "Diagnostic Procedures for Viral and Rickettsia Infections," Amer. Publ. Health Assoc, Inc., 1969, Fourth Edition, pp 653-655, 659-660, and 570-572
44 ✓	Fong <i>et al.</i> (1991) "Advantages of multiple cell culture systems for detection of mixed-virus infections," <i>J. Virol. Methods</i> 33:283-289
45 ✓	Tougianidou <i>et al.</i> (1989) "Assessment of Various Cell Lines (including Mixed Cell Cultures) for the Detection of Enteric Viruses in Different Water Sources," <i>Water Science and Tech.</i> 21:311-314
46 ✓	Subrahmanyam <i>et al.</i> (1974) "The Development of Double Seeded and Mixed Cell Culture Systems for Use in Diagnostic Virology," <i>Archiv Fuer Die Gesamte Virusforschung</i> 44:291-297

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- | | | |
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| 47 | ✓ | Huang <i>et al.</i> (2000) "Application of mixed cell lines for the detection of viruses from clinical specimens," Clin. Microbiol. Newsletter 22:89-92 |
| 48 | ✓ | Reina <i>et al.</i> (1997) "Comparison of Madin-Darby canine kidney cells (MDCK) with a green monkey continuous cell line (Vero) and human lung embryonated cells (MRC-5) in the isolation of influenza A virus from nasopharyngeal aspirates by shell vial culture," J. Clin. Microbiol. 35:1900-1901 |
| 49 | ✓ | Schultz-Cherry <i>et al.</i> (1998) "Mink lung epithelial cells: Unique cell line that supports influenza A and B virus replication," J. Clin. Microbiol. 36:3718-3720 |
| 50 | ✓ | Huang <i>et al.</i> (2000) "Mink lung cells and mixed mink lung and A549 cells for rapid detection of influenza virus and other respiratory viruses," J. Clin. Microbiol. 38:422-423 |
| 51 | ✓ | Rangan <i>et al.</i> (1972) "Detection and assay of feline leukemia virus (FeLV) by a mixed culture cytopathogenicity method," Virol. 47:247-250 |
| 52 | ✓ | Karemyi <i>et al.</i> (1982) "Use of a co-cultivation method for detecting cytomegalovirus contamination of cell cultures of simian origin," Voprosy Virusdologii 27(2), Abstract |
| 53 | ✓ | Scholl <i>et al.</i> , U.S. Application No. 20030215796 published 11/20/03 |
| 54 | ✓ | Chan <i>et al.</i> (2003) "Human Metapneumovirus Detection in Patients with Severe Acute Respiratory Syndrome," Emerging Infec. Dis. 9:1058-1063 |
| 55 | ✓ | Frank <i>et al.</i> (1979) "Comparison of Different Tissue Cultures for Isolation and Quantitation of Influenza and Parainfluenza Viruses," J. Clin. Microbiol. 10:32-36 |
| 56 | ✓ | Setterquist <i>et al.</i> "A Comparison of LLC-MK2 and R-Mix™ (A549, MV1lu) Cells for the Detection of Human Metapneumovirus," 19th Annual Clinical Virology Symposium, Clearwater, FL, April 27-30, 2003 |
| 57 | ✓ | Genomes, T.A. Brown, Wiley-Liss, 1994, page 179 |
| 58 | ✓ | Biochemistry, Third Edition, W.H. Freeman and Company, NY, 1988, page 98 |
| 59 | ✓ | The Encyclopedia of Molecular Biology, Blackwell Science, 1994, page 225 |

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